Application No.: 10/615,010 31 Docket No.: 03818/100L651-US1

REMARKS

A second Supplemental IDS is also with this response. It contains several references cited in the European Search Report of a related case. The search report was mailed by the office to the undersigned on August 26, 2004 and an IDS filed concurrently with this amendment is therefore timely.

I. Claim Status

Prior to this amendment, Claims 1-38 are pending. Claims 3 and 4 have been cancelled without prejudice. Claims 1, 2, 6-32, 34 and 38 have been amended. Claim 1 has been amended to incorporate the definitions for M and D found in original claims 2 and 4. Claim 2 has been amended to incorporate the general Formula I from original claim 1 and the definitions for L and D from original claims 3 and 4. Claim 2 has further been amended to include pharmaceutically acceptable salts and solvates. Support for this amendment comes from the specification as filed at page 1 lines 17-18, page 5 lines 8-11 and page 9 lines 8-9. Claims 6 and 7 have been amended to correct dependency because claims 3 and 4 from which claims 6 and 7 depended previously have been canceled. Claims 8-30 have been amended to add the phrase "and pharmaceutically acceptable salts or solvates thereof." Support for this amendment can be found in the specification as filed at page 1 lines 17-18, page 5 lines 8-11 and page 9 lines 8-9. Claim 31 has been amended to recite the definitions for M and D found in original claims 2 and 4. Minor amendments have been made to claims 32, 34 and 38 all of which are now dependent on claim 1. No new matter has been added by these amendments.

I. Claim Rejections

a. 35 U.S.C. §112 First Paragraph

Claims 1-7 and 31-38 stand rejected under 35 USC §112 first paragraph. The Examiner contends that while being enabled for a compound where M is a macrolide of Formula II, L is a group of Formula IV and D is derived from NSAIDS the specification does not reasonably provide enablement for M being a macrolide, D being a nonsteroidal subunit and L being any linker.

Without conceding that the Examiner's position was correct, claim 1 has been amended to now recite the definitions for M and D originally found in claims 2 and 4. Applicants submit that the features of M and D (as presented in original claims 2 and 4) and L (as originally filed in claim 1) are fully enabled. Applicants submit that many examples of linker molecules are given in the specification and genus of claim 2 and the construction of the present conjugates using these linkers has been generally described and exemplified. (see pages 23-32) Applicants submit that based on this extensive teaching of the present specification a person of ordinary skill can readily select any number of appropriate linker molecules. Accordingly, the breadth of claim 1 is amply enabled by the specification. Claim 2 has been amended to recite in addition to the definition of M as a macrolide of Formula II the definitions for L being a group of Formula IV originally found in claim 3 and D being the group of NSAIDS originally found in claim 4. Claim 31 has been amended to recite a process for the preparation of compounds within amended claim 1. Applicants respectfully request reconsideration and withdrawal of this rejection.

b. 35 U.S.C. §112 Second Paragraph Rejections

Claims 8-30 stand rejected under 35 U.S.C. §112 second paragraph for failing to end in a period.

Claims 8-30 have been amended to include a period. Applicants respectfully request reconsideration and withdrawal of this rejection.

Claim 31 has been rejected under 35 U.S.C. §112 second paragraph for failing to recite definitions for the M, L and D groups. Claim 31 has been amended to recite definitions for the M, L and D groups. Applicants respectfully request reconsideration and withdrawal of this rejection.

Non-statutory Double Patenting Rejection

Claims 1-38 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-52 of copending Application No. 10/616,046. The Examiner contends that although the conflicting claims are not identical they

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are not patentably distinct from each other because the compounds of the instant application are

encompassed by the compounds of the copending application. Without conceding the Examiner's

position, concurrent with the filing of this amendment, applicants also file a terminal disclaimer in

compliance with 37 CFR 1.32(c).

c. 35 U.S.C. §102(a) Rejection

Claim 1 stands rejected under 35 U.S.C. §102(a) as being anticipated by Griffin (U.S.

Patent 6,566,509). Claim 1 has been amended to incorporate the limitations found in original

claims 2 and 4. Amended claim 1 therefore cannot be anticipated by Griffin. Applicants

respectfully request removal of this rejection.

Conclusion

It is believed that the application is now in condition for allowance. Favorable action is

earnestly solicited. If the Examiner believes a telephonic interview would expedite the prosecution

of the instant case, she is invited to call the applicants' representative whose contact information

appears below.

Dated: November 10, 2004

Respectfully submitted.

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